



Billing Code: 4160

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

**[Docket No. FDA – 2017 – N – XXXX]**

#### **Statement of Organization, Functions, and Delegations of Authority**

**AGENCY:** Office of Regulatory Affairs,

Office of Global Regulatory Operations and Policy, Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA), Office of Global Regulatory Operations and Policy, Office of Regulatory Affairs (ORA), Office of Regulatory Science (ORS), and all ORA Laboratories have modified the structure. This new organizational structure was approved by the Secretary of Health and Human Services and effective on June 6, 2016.

**FOR FURTHER INFORMATION CONTACT:** Paul Norris, DVM, MPA, Director, Office of Regulatory Science, Office of Regulatory Affairs, Office of Global Regulatory Operations and Policy, Food and Drug Administration, NCTR-50 Room 404, Jefferson, Arkansas 72079, Phone: 870-543-4099.

#### **I. Summary**

Part D, Chapter D-B (Food and Drug Administration), the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services 35 FR 3685, dated February 25, 1970; 60 FR 56605, dated November 9, 1995; 64 FR 36361, dated July 6, 1999; 72 FR 50112, dated August 30, 2007; 74 FR 41713, dated August 18, 2009; and 76 FR 45270, dated July 28, 2011, is amended to reflect the reorganization of the Office of Regulatory Affairs and the Office of Regulatory Science (ORS), and all ORA Laboratories in this consolidation.

This organization expands current activities in the Office of Regulatory Science and ORA's Laboratories in support of the Agency's Program Alignment Initiative. One of the key elements outlined in the initiative is to transition to distinct commodity-based and vertically integrated regulatory programs with well-defined leads, promoting coherent policy and strategic development. This transforms the regionally organized laboratory system into a true national resource with enhanced ability to meet its public health mission to provide diverse scientific expertise, leadership, and responsive quality analytical services to safeguard public health in a global environment and foster continued flexibility across its functions and programs. It also centralizes and streamlines laboratory operations, scientific research, and support functions into one Office of Regulatory Science. Operationally this facilitates a more efficient and strategic deployment of these resources during public health emergencies and food borne outbreaks. Centralizing the laboratory system greatly enhances command and control of laboratory functions.

The Food and Drug Administration, Office of Global Regulatory Operations and Policy, Office of Regulatory Affairs (ORA), Office of Regulatory Science (ORS) has been restructured as follows:

DLLRK. ORGANIZATION. The Office of Regulatory Science is headed by the Director, Office of Regulatory Science and includes the following organizational units:

Office of Regulatory Science (DLLRK)

Automated Laboratory Management Staff (DLLRK1)

Safety and Risk Management Staff (DLLRK2)

Office of Research Coordination and Evaluation (DLLRKA)

Scientific Research Staff (DLLRKA1)

Evaluation Staff (DLLRKA2)

Office of Medical Products, Tobacco, and Specialty Laboratory Operations (DLLRKB)

Medical Products and Tobacco Scientific Staff (DLLRKB1)

Forensic Chemistry Center (DLLRKBA)

Inorganic Branch (DLLRKBA1)

Organic Branch (DLLRKBA2)

Winchester Engineering and Analytical Center (DLLRKBB)

Analytical Branch (DLLRKBB1)

Engineering Branch (DLLRKBB2)

Detroit Laboratory (DLLRKBC)

Northeast Medical Products Laboratory (DLLRKBD)

Pacific Southwest Medical Products Laboratory (DLLRKBE)

Philadelphia Laboratory (DLLRKBF)

San Juan Laboratory (DLLRKBG)

Southeast Tobacco Laboratory (DLLRKBH)

Office of Food and Feed Laboratory Operations (DLLRKC)

Food and Feed Scientific Staff (DLLRKC1)

Arkansas Laboratory (DLLRKCA)

Chemistry Branch I (DLLRKCA1)

Chemistry Branch II (DLLRKCA2)

Microbiology Branch (DLLRKCA3)

Denver Laboratory (DLLRKCB)

Chemistry Branch (DLLRKCB1)

Microbiology Branch (DLLRKCB2)

Kansas City Laboratory (DLLRKCC)

Chemistry Branch I (DLLRKCC1)

Chemistry Branch II (DLLRKCC2)

Northeast Food and Feed Laboratory (DLLRKCD)

Chemistry Branch I (DLLRKCD1)

Chemistry Branch II (DLLRKCD2)

Microbiology Sciences Branch (DLLRKCD3)

Pacific Northwest Laboratory (DLLRKCE)

Chemistry Branch (DLLRKCE1)

Microbiology Branch (DLLRKCE2)

Applied Technology Branch (DLLRKCE3)

San Francisco Laboratory (DLLRKCF)

Chemistry Branch (DLLRKCF1)

Microbiology Branch (DLLRKCF2)

Southeast Food and Feed Laboratory (DLLRKCG)

Microbiology Branch (DLLRKCG1)

Nutrient Analysis Branch (DLLRKCG2)

Chemistry Branch (DLLRKCG3)

Pacific Southwest Food and Feed Laboratory (DLLRKCH)

Chemistry Branch (DLLRKCH1)

Microbiology Branch (DLLRKCH2)

## **II. Delegations of Authority**

Pending further delegation, directives, or orders by the Commissioner of Food and Drugs, all delegations and redelegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further redelegations, provided they are consistent with this reorganization.

## **III Electronic Access**

Persons interested in seeing the complete Staff Manual Guide can find it on FDA's website at:

<http://www.fda.gov/AboutFDA/ReportsManualsForms/StaffManualGuides/default.htm>

Dated: December 21, 2017.

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Eric D. Hargan

Acting Secretary of Health and Human Services

